AE Detection and Creation (RP15) Post accessioning & baseline assessment of study participant; usually post a treatment cycle. Directed to complete Pull Patient **CTCAE Data Collection** Medical Record, Form per Protocol Access EMR. Or Schedule from Source other patient Documentation (pt. Med documentation Rec) **RP 16** Pt/Family Care Giver Record the report of AE **Treating** Clinical AE in the Pt Medical Record MD / EMR or other CRA/ document Nurse Direct observation Treating of AE Clinician observation of the AE Create a candidate AE Candidate AE data stored Protocol Staff notified for **CaAERS** follow-up AE is in candidate state Automated CTC Grading (Quantitative Dev by: COH National Medical Center 1 of 3 DRAFT -2/04/05

AE Detection and Creation (RP16) Post accessioning & baseline assessment of study participant; usually post a treatment cycle. Log into AERS / Create AE. (Use AE Data Collection (Use RP 22 CTMS - select pt Case 1.5 is the Create Case 1.6) **RP 16** or protocol minimum amt of AE? Choose 'Enter data needed to AE for pt" (Use create the AE) Cases; 1.11 1.12) Candidate AE **Treating** data stored MD / Domain expert driven CRA / report selection: Nurse Protocol staff notified Minimal dataset to generate reports & available for query/ select what report to audit complete (maybe in addition to those recommended by triggers) Generation of reports and Notification report data AE is in Pending State Triggers sets (Use Execute and Case 4.2-Update as Trigger and/ data is or User Preconditions: collected driven Institution, Sponsor and selection Preconditions: Protocol Specific **CaAERS** Protocol and Study Preconditions: *Single AE Notification Triggers are Participant created/ Report formats/data or Batched defined (Use cases imported and linked; collections forms are 1.9, 1.10, 1.11) (Use Cases 1.1, configured (Use Case *Outcome of trigger is 1.2, 1.3, 1.4) 4.1) *Templates for what report to invoke common external and when reporting agencies provided-expedited and annual reviews

2 of 3

DRAFT -2/04/05

Dev by: COH National Medical Center

AE Signoff and Report Submission (RP22)

Post accessioning & baseline assessment of study participant; usually post a treatment cycle.

